

Patent Appl. No. 10/647,919
Docket No. 15634 (PC25246)
Filing Date: August 26, 2003

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REMARKS

MAR 21 2007

I. Preliminary Remarks

The Claims were subject to a Restriction Requirement, mailed March 9, 2006. Applicant chose Group I, Claims 1-11, 20-31 and 76-83, drawn to an immunogenic/vaccine composition, and elected the species of *Leptospira borgpetersenii hardjo-bovis*.

After entry of this paper, Claims 3 and 22 are original. Claims 1-2, 4-5, 7-11, 20-21, 23, 25-31, 76-77, and 79-82 are amended. Claims 6, 12-19, 24, 26, 32-75, 78, and 83 are withdrawn, with claims 6, 12, 18, 24, 26, 54, 70-72, 78, and 83 being withdrawn and amended. Withdrawn claims are withdrawn without prejudice in an effort to favorably advance prosecution of the present application. Applicant reserves the right to pursue the subject matter of the withdrawn claims in a continuation application, or to have the withdrawn claims rejoined in the current application. Support for the amendments to the claims is found throughout the specification. The amendments do not include new matter. Reconsideration and withdrawal of the rejections are solicited for the reasons set out below.

In this response, Applicant addresses each of the rejections raised by the Examiner. Applicant therefore respectfully submits that the present application is in condition for allowance. Favorable consideration of all pending claims is respectfully requested.

This Response is timely filed. The USPTO is given authorization to charge Deposit Account No. 16-1445 for any fees necessary with the submission of this Response.

II. Patentability Arguments

A. The anticipation rejection of Claims 1-2, 7, 20-21, 76, and newly amended claims 8-11, 28-31, and 80-82 under 35 U.S.C. §102(b) may properly be withdrawn.

A patent is invalid for anticipation under 35 USC 102(b) if a single prior art reference identically discloses each and every limitation of the invention as set forth in the claims. (Lewmar Marine, Inc. v. Barient, Inc., 827 F.2d 744, 747 (Fed. Cir. 1987)). The prior publication must disclose in an enabling manner the invention that is in question. The exclusion of a claimed element, no matter how insubstantial or obvious, from a reference is enough to negate anticipation. (Connell v. Sears, Roebuck & Co., 220 U.S.P.Q. 193, 1098 (Fed. Cir. 1983)). Applicant respectfully submits that these criteria are not met in the Examiner's rejection. The claims, therefore, are not anticipated by the references.

Patent Appl. No. 10/647,919
 Docket No. 15634 (PC25246)
 Filing Date: August 26, 2003

The Examiner has maintained the rejection of claims 1-2, 7, 20-21, 27, 76 and newly amended claims 8-11, 28-31, and 80-82 under 35 U.S.C. 102(b) as being anticipated by Bowland, et al., of record (Canadian Veterinary Journal, Jan 2000, Vol. 41, No. 1, pages 33-48). The Examiner has disagreed with our contention in the response to the Office Action of May 1, 2006 that Bowland, et al., do not teach the antigen composition of the present invention comprising two different inactivated BVDV antigens, namely BVDV Type 1 and BVDV Type 2. The Examiner stated that "The commercial vaccine BoviShield™3 referenced in Table 1 (page 35) contains BVDV Type 1 and BVDV Type 2. Therefore Bowland does teach the instant claimed invention." We respectfully disagree with the conclusion reached by the Examiner as far as the antigen composition of the commercial vaccine BoviShield™3.

As stated above, a rejection of a claim for anticipation requires that the single cited reference disclose each and every element of the claim in an enabling manner. Bowland, et al., do not anticipate the claimed invention because they fail to disclose each and every element of the claim in an enabling manner. Bowland, et al., do not enable an immunogenic composition or a vaccine composition comprising two different strains (Types 1 and 2) of BVD virus. They merely reference BoviShield™3 and indicate that it contains IBRV, PI3 and BVDV. Bowland, et al., do not teach that BoviShield™3 contains both BVDV Types 1 and 2. As indicated by the sub-heading within Table 1 of Bowland, et al., (Line 21, Page 35) BoviShield™3 is categorized as a 3-Way MLV vaccine, thus containing 3 viral antigens. The Examiner would need to look to another reference to determine whether both Types are included in BoviShield™3. However, this is not the standard for an anticipation rejection. Details about the antigenic composition of BoviShield™3 can be found on page 1145 of Compendium of Veterinary Products, Eighth Edition published January 2005 (ISBN 1-889750-81-6 and Library of Congress Card Number: 97-643262 – See attached). According to this description, "BoviShield™3 is a freeze-dried preparation of modified live virus (MLV) strains of IBR, BVD, and PI₃ viruses, plus a sterile diluent used to rehydrate the freeze-dried vaccine." Even this reference does not state whether the preparation contains Type 1, Type 2, or both. Also the viral antigens contained in BoviShield™3 are only IBRV, PI3 and BVDV. It does not contain all of the viral antigens contained in the compositions of

Patent Appl. No. 10/647,919
 Docket No. 15634 (PC25246)
 Filing Date: August 26, 2003

the present invention, which include BHV-1, PI3, BRSV, BVDV-1, and BVDV-2 (see Claims 1, 20, and 76 of the instant invention).

Also indicated by the sub-heading within Table 1 of Bowland, et al., (Line 21, Page 35) BoviShield™3 is categorized as a 3-Way MLV vaccine. The term MLV stands for “Modified Live Virus” as opposed to inactivated virus. While BoviShield™3 is a composition containing a modified live BVD viral antigen, Claims 2, 21, 80, and 82 of the instant invention are drawn to antigen compositions comprising two different inactivated strains (Types 1 and 2) of BVD virus. Thus, Bowland, et al., do not anticipate these claims of the instant invention.

Thus, Bowland, et al., do not teach each and every limitation of Claims 1, 20, or 76 of the instant application. The other rejected claims either depend from one of these independent claims or from a claim that depends from them. These dependent claims further delineate the independent claims; they embody all the elements of them. Accordingly, the subject matter of the dependent claims is not anticipated by Bowland.

Thus, based on the remarks presented herein, the rejection of Claims claims 1-2, 7, 20-21, 27, 76 and newly amended Claims 8-11, 28-31, and 80-82 under 35 U.S.C. 102(b) is overcome. Withdrawal of the rejection is therefore respectfully requested.

C. The Obviousness Rejection of Claims 1-7, 20-27, 76-79 83 under 35 U.S.C. §103(a) May Be Properly Withdrawn.

As stated in the MPEP (§2141), to support an obviousness rejection, four basic criteria must be met. These are (A) The claimed invention must be considered as a whole; (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; (C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and (D) Reasonable expectation of success is the standard with which obviousness is determined. Clearly for prior art to render an invention obvious, it must render obvious the whole invention and not merely some part of the invention (*In re Antonie* 559 F.2d 618, 620, 195 USPQ 6,8 (CCPA 1997)). The prior art must also be considered as a whole including parts that teach away from Applicant’s invention. Applicant respectfully submits that these criteria are not met in the Examiner’s rejections.

Patent Appl. No. 10/647,919
 Docket No. 15634 (PC25246)
 Filing Date: August 26, 2003

The Examiner has maintained that Claims 1-7, 20-27, 76-79, 83 and newly amended claims 8-11, 28-31 and 80-82 are unpatentable over Talens, et al., (Journal of the American Veterinary Medical Association, May 1, 1989, Vol. 194, No. 9, pages 1273-1280) or Bowland, et al., as originally applied to claims 1-2, 7, 20, 21, 27 and 76, and further in view of Barr, et al., (Advanced Drug Delivery Reviews, 1998, Vol. 32, No. 3, pages 247-271), Pruett, et al., (Veterinary Parasitology, 1995, Vol. 58, No. 1-2, pages 143-153), and Wilson, et al., (Canadian Journal of Veterinary Research, Oct 1995, Vol. 59, No. 4, pages 299-305). Applicants respectfully traverse this rejection.

The compositions of the present invention comprise a group of antigens and a chemically well-defined adjuvant component. The antigens of the present invention are three different modified live viruses, namely Bovine Herpes Virus (BHV), Bovine Respiratory Syncytial virus (BRSV), and parainfluenza virus 3 (PI3) and two different stains of BVD virus. The adjuvant composition is made up of Amphigen, an oil-in-water emulsion, and Quil A, a triterpenoid.

The Examiner stated that Talens, et al., and Bowland, et al., teach the antigen composition of the present invention, and that the adjuvant composition of the present invention can be learned from Barr, et al., Pruett, et al., and Wilson, et al. As explained in our response dated July 14, 2006 to the Office Action dated May 1, 2006, as well as in this present response, neither Talens, et al., nor Bowland, et al., teaches the antigen compositions of the present invention. The antigen composition claimed in the present invention is a mixture of two BVD viral antigens whereas both references cited by the Examiner contain only one strain of BVD viral antigen or do not specify the type of BVD viral antigen. See discussion above.

The Examiner has cited Barr et al., Pruett et al., and Wilson, et al., as prior art references teaching the adjuvant composition of the present invention. According to the examiner, a person skilled in the art could use the teachings about adjuvant compositions in one of these three references and with the teachings of either Talens, et al., or Bowland, et al., reach the vaccine compositions of the present invention. We respectfully disagree with the contention of the examiner.

Patent Appl. No. 10/647,919
 Docket No. 15634 (PC25246)
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As established in our response to the Office Action of May 1, 2006, as well as in this response, neither Talens, et al., nor Bowland, et al., teaches the antigen compositions claimed in the present application. Even if we assume that either one of these cited references does teach the antigen composition of the present invention, it can not be concluded that a person skilled in the art could combine their teachings with the teachings about adjuvants in the other three references to reach a vaccine composition of the present invention because neither Barr et al., Pruett et al., nor Wilson, et al., teach nor suggest the adjuvant compositions of the present invention.

The present invention claims an adjuvant composition comprising an oil-in-water emulsion (such as Amphigen) and Quil A (a saponin). Barr, et al., teaches in general about the chemistry and the mode of action of saponin adjuvants. This reference also teaches the preparation and use of immunostimulatory complexes (ISCOM) based on saponin adjuvant. While it teaches the use of Quil A in combination with liposomes, microspheres, and aluminum salts, there is neither a teaching nor a suggestion for combining Quil A with an oil-in-water emulsion such as Amphigen.

Pruett, et al., teach a combination of Amphigen and alhydrogel as an adjuvant in a vaccine formulation comprising hypodermin A protein as an antigen. There is no teaching in this reference for combining Quil A with Amphigen. Moreover, this reference focused on showing a synergy in the antibody response due to this Amphigen-Alhydrogel combination. A person skilled in making viral vaccines would have paid attention towards selecting an adjuvant combination based on the synergy in terms of cellular immune response, as the cellular immune response is more important in offering protective immune response due to vaccination. Pruett, et al., suggest the mixture of alhydrogel and amphigen to be worthy of further efficacy investigation in a vaccine formulation only with hypodermin A. There is nothing in Pruett to suggest that the adjuvants used in the cattle grub hypodermin A homogenate vaccine could be used successfully in the compositions of the present invention. Thus a person skilled in the art would not have combined the teachings of Pruett, et al., to prepare a vaccine of present invention.

Wilson, et al., teach the use of a variety of adjuvants in testing the subunit vaccines prepared from extracts of Actinobacillus pleuropneumoniae. Included in the list of adjuvants

Patent Appl. No. 10/647,919
Docket No. 15634 (PC25246)
Filing Date: August 26, 2003

tested in this study are Amphigen and Quil A. However, in this reference there was no suggestion to combine Amphigen with Quil A. In one of the animal trials in this study (Trial III, Page 303) Amphigen was used either alone or in combination with vitamin E. As the results shown in the Table III on page 303 indicates, combining Vitamin E with Amphigen significantly reduced the adjuvanticity of Amphigen. With the addition of Vitamin E to Amphigen, the protective immune response, measured in terms of antibody titer, decreased while the mortality rate increased. At the same time addition of Vitamin E to Canola improved the protective immune response. Thus a person skilled in the art, upon seeing the results of Wilson, et al., would be resistant to combine any other adjuvant component with Amphigen in a vaccine formulation.

The MPEP (2143.01) teaches that the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. (Also see *In re Fritch* (CAFC 1992) 972 F2d 1260, 23 PQ2d 1780 and *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH* (CAFC 1989), 139 F3d 877, 45 PQ2d 1977.) However, there is no such suggestion in the references of the desirability of combining the references.

Claims 6, 24, 26, and 78 have been withdrawn, rendering this rejection moot.

The Applicant respectfully submits that none of the references cited by the Examiner suggest Applicant's invention. There is no indication in any of the references that would suggest that the references be combined. Moreover, even when combined the references do not yield Applicant's invention. Accordingly, it is respectfully submitted that the immunogenic compositions and vaccine compositions, as presently claimed, are not rendered obvious by Talens, et al., or Bowland, et al., in view of Barr, et al., Pruett, et al., and Wilson, et al. Thus, based on the remarks presented herein, the rejection of Claims 1-7, 20-27, 76-79, 83 and newly amended claims 8-11, 28-31 and 80-82 under 35 U.S.C. §103(a) is overcome. Withdrawal of the rejection is respectfully requested.

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III. Conclusion.

In view of the amendments and remarks made herein, Applicants respectfully submit that Claims 1-5, 7-11, 20-23, 25-31, 76-77, and 79-82 are in condition for allowance and request expedited notification of same.

Respectfully submitted,



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Date: March 21, 2007

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BOVI-PLAZ™

AgriPharm

Mycoplasma Bovis Bacterin

Contains: This product contains the antigen(s) above.

Indications: For use in healthy stocker and feeder calves four months of age or older as an aid in the prevention and control of respiratory disease due to Mycoplasma Bovis.

Dosage and Administration: Instructions: Shake well and aseptically inject 2 mL subcutaneously in the side of the neck. Repeat on days 7 and 14 alternating sides of the neck.

Precautions: Store at 2° to 7°C. Do not use if contents are broken as indicated by separation at the bottom of bottle. Use entire contents when opened.

Caution(s): Efficacy was determined by challenge 21 days after the final vaccination, duration of immunity is unknown. Do not contaminate with dirt or chemicals.

May cause local swelling. In case of anaphylactic reaction treat symptomatically.

For animal use only. For veterinary use only.

Warning(s): Do not inject into muscle, may cause carcass trim. Do not vaccinate within 60 days of slaughter. Keep out of reach of children.

Preservatives: 50 doses (100 mL) and 100 doses (200 mL).

Manufactured by: Texas Vet Lab, Inc.

NAC No.: 14371430

Bacterin

BOVI-SERA SERUM ANTIBODIES

Colorado Serum

Antiserum
Adjuvanted Pyrogen-Free Escherichia Coli-Metaphase Rheumatoid-Factorial Molluscicide-
Jelminase Pyriminase Antibody, Bovine Isolates, Bovine Origin

U.S. Vet. Lic. No.: 168

Contains: This product contains the antigen(s) above.

Indications: For use as an aid in the prevention and treatment of enteric and respiratory conditions caused by the micro-organisms named.

Dosage and Administration: Inject subcutaneously or intramuscularly.

Prevention: Calves: 20-40 mL as soon after birth as possible. Cattle: 50-75 mL.

Sheep: 10-15 mL.

Treatment: Calves: 40-100 mL. Cattle: 75-150 mL. Sheep: 20-40 mL. Administer at 12-24 hour intervals until improvement is noted.

Precautions: Store at 2° to 7°C. Do not freeze. Shake well before use. Use entire contents when first opened.

Caution(s): Anaphylactic reaction may occur following administration of products of this nature. (Note: administer epinephrine or equivalent. For veterinary use only.)

Warning(s): Do not vaccinate within 21 days before slaughter.

Preservatives: 20 mL, 250 mL and 1,000 mL bottles.

NAC No.: 11010022

803 4-03

BOVI-SHIELD™ 3

Pfizer Animal Health

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza Vaccine, Modified Live Virus

U.S. Vet. Lic. No.: 169

Description: BOVI-SHIELD™ 3 is a freeze-dried preparation of modified live virus (MLV) strains of IBR, BVD, and PI viruses, plus a sterile diluent used to rehydrate the freeze-dried vaccine. Viral antigens are propagated on established cell lines.

Contains gentamicin as preservative.

Indications: BOVI-SHIELD™ 3 is for vaccination of healthy, nonpregnant cattle as an aid in preventing infectious bovine rhinotracheitis (IBR) virus, bovine viral diarrhea (BVD) virus, and disease caused by parainfluenza (PI) virus.

Directions:

1. General Directions: Vaccination of healthy, nonpregnant cattle is recommended. Aseptically rehydrate the freeze-dried vaccine with the sterile diluent provided, shake well, and administer 2 mL intramuscularly. In accordance with Best Quality Assurance guidelines, this product should be administered in the muscular region of the neck.

2. Primary Vaccination: Administer a single 2 mL dose to healthy cattle.

3. Revaccination: Annual revaccination with a single dose is recommended.

4. Good animal husbandry and best health management practices should be employed.

Precautions: Store at 2°-7°C. Prolonged exposure to higher temperatures and/or direct sunlight may adversely affect potency. Do not freeze.

Use entire contents when first opened.

Sterilized syringes and needles should be used to administer this vaccine. Do not sterilize with chemicals because traces of disinfectant may inactivate the vaccine.

Use containers and all unused contents.

Caution(s): Do not use in pregnant cows (abortions can result) or in calves nursing pregnant calves.

As with many vaccines, anaphylaxis may occur after use. Initial antidote of epinephrine is recommended and should be followed with appropriate supportive therapy.

This product has been shown to be efficacious in healthy animals. A protective immune response may not be elicited if animals are incubating an infectious disease, are malnourished or parasitized, are stressed due to shipment or environmental conditions, are otherwise immunocompromised, or the vaccine is not administered in accordance with label directions.

Warning(s): Do not vaccinate within 21 days before slaughter.

For veterinary use only.

Description: Disease Description: IBR, BVD, and PI viruses are commonly associated with respiratory disease and/or reproductive failure in cattle. IBR virus infection is characterized by high temperature, excessive nasal discharge, conjunctivitis and ocular discharge, inflamed nose ("red nose"), increased rate of respiration, coughing, loss of appetite, and depression. Cattle infected during pregnancy may abort.

BVD virus may be transmitted in nasal secretions, saliva, blood, feces, and/or urine, and by direct contact with contaminated objects; it invades through the nose and mouth and replicates systemically. Infection during pregnancy may result in abortion, fetal resorption, or congenital malformation of the fetus. Moreover, B susceptible cows are infected with noncytopathic BVD virus during the first trimester of pregnancy, their calves may be born persistently infected with the virus. Exposure of these calves to certain virulent cytopathic BVD virus strains may precipitate BVD-mucosal disease. Clinical signs of BVD include loss of appetite, abortions in the month, profuse salivation, elevated temperature, diarrhea, dehydration, and lameness.

PI virus usually localizes in the upper respiratory tract, causing elevated temperature and moderate nasal and ocular discharge. Although clinical signs typically are mild, PI infection

weakens respiratory tissues, invasion and replication of other pathogens, particularly Pasteurella spp., is thereby facilitated and may result in pneumonia.

Field Data: Safety and Efficacy: In safety studies of the fractions of BOVI-SHIELD™ 3, no adverse reactions to vaccination were observed.

Efficacy of each fraction of BOVI-SHIELD™ 3 was demonstrated in challenge-of-immunity studies. Cattle vaccinated with any fraction of BOVI-SHIELD™ 3, followed by challenge with a disease-causing strain of that fraction, showed no signs or had significantly fewer clinical signs than nonvaccinated control cattle. Serologic studies demonstrated no immunologic interference among the fractions of BOVI-SHIELD™ 3.

Preservatives: 10 dose and 50 dose vials.

NAC No.: 36900430

75-4148-01

BOVI-SHIELD™ 4

Pfizer Animal Health

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza-Respiratory Syncytial Virus Vaccine, Modified Live Virus

U.S. Vet. Lic. No.: 169

Description: BOVI-SHIELD™ 4 is a freeze-dried preparation of modified live virus (MLV) strains of IBR, BVD, PI, and BRSV viruses, plus a sterile diluent used to rehydrate the freeze-dried vaccine. Viral antigens are propagated on established cell lines.

Contains gentamicin as preservative.

Indications: BOVI-SHIELD™ 4 is for vaccination of healthy, nonpregnant cattle as an aid in preventing infectious bovine rhinotracheitis caused by infectious bovine rhinotracheitis (IBR) virus, bovine viral diarrhea (BVD) virus, and disease caused by parainfluenza (PI) virus and bovine respiratory syncytial virus (BRSV).

Directions:

1. General Directions: Vaccination of healthy, nonpregnant cattle is recommended. Aseptically rehydrate the freeze-dried vaccine with the sterile diluent provided, shake well, and administer 2 mL intramuscularly. In accordance with Best Quality Assurance guidelines, this product should be administered in the muscular region of the neck.

2. Primary Vaccination: Administer a single 2 mL dose to healthy cattle, followed by a second dose of BOVI-SHIELD™ 4 3-4 weeks later.

3. Revaccination: Annual revaccination with a single dose is recommended.

4. Good animal husbandry and best health management practices should be employed.

Precautions: Store at 2°-7°C. Prolonged exposure to higher temperatures and/or direct sunlight may adversely affect potency. Do not freeze.

Use entire contents when first opened.

Sterilized syringes and needles should be used to administer this vaccine. Do not sterilize with chemicals because traces of disinfectant may inactivate the vaccine.

Use containers and all unused contents.

Caution(s): Do not use in pregnant cows (abortions can result) or in calves nursing pregnant cows.

As with many vaccines, anaphylaxis may occur after use. Initial antidote of epinephrine is recommended and should be followed with appropriate supportive therapy.

This product has been shown to be efficacious in healthy animals. A protective immune response may not be elicited if animals are incubating an infectious disease, are malnourished or parasitized, are stressed due to shipment or environmental conditions, are otherwise immunocompromised, or the vaccine is not administered in accordance with label directions.

Warning(s): Do not vaccinate within 21 days before slaughter.

For veterinary use only.

Description: Disease Description: IBR, BVD, PI, and BRSV viruses are commonly associated with respiratory disease and/or reproductive failure in cattle. IBR virus infection is characterized by high temperature, excessive nasal discharge, conjunctivitis and ocular discharge, inflamed nose ("red nose"), increased rate of respiration, coughing, loss of appetite, and depression.

Cattle infected during pregnancy may abort.

BVD virus may be transmitted in nasal secretions, saliva, blood, feces, and/or urine, and by direct contact with contaminated objects; it invades through the nose and mouth and replicates systemically. Infection during pregnancy may result in abortion, fetal resorption, or congenital malformation of the fetus. Moreover, B susceptible cows are infected with noncytopathic BVD virus during the first trimester of pregnancy, their calves may be born persistently infected with the virus. Exposure of these calves to certain virulent cytopathic BVD virus strains may precipitate BVD-mucosal disease. Clinical signs of BVD include loss of appetite, abortions in the month, profuse salivation, elevated temperature, diarrhea, dehydration, and lameness.

PI virus usually localizes in the upper respiratory tract, causing elevated temperature and moderate nasal and ocular discharge. Although clinical signs typically are mild, PI infection weakens respiratory tissues, invasion and replication of other pathogens, particularly Pasteurella spp., is thereby facilitated and may result in pneumonia.

BRSV is the etiologic agent of a specific viral respiratory disease of cattle of all ages, including nursing calves. Infection is characterized by rapid breathing, coughing, loss of appetite, discharge from the nose and eyes, fever, and swelling around the throat and neck in an acute outbreak. Deaths may follow within 48 hours after onset of signs. Clinically, BRSV infection may be indistinguishable from other viral infections associated with the bovine respiratory disease complex. BRSV infection, like PI, facilitates invasion and replication of other respiratory pathogens. Exacerbation of clinical signs has been documented when concurrent BRSV and BVD or IBR infections exist.

Field Data: Safety and Efficacy: In safety studies of the fractions of BOVI-SHIELD™ 4, no adverse reactions to vaccination were observed.

Efficacy of each fraction of BOVI-SHIELD™ 4 was demonstrated in challenge-of-immunity studies. Cattle vaccinated with any fraction of BOVI-SHIELD™ 4, followed by challenge with a disease-causing strain of that fraction, showed no signs or had significantly fewer clinical signs than nonvaccinated control cattle. Serologic studies demonstrated no immunologic interference among the fractions of BOVI-SHIELD™ 4.

Preservatives: 5 dose, 10 dose and 50 dose vials.

NAC No.: 36900441

75-4156-02

BOVI-SHIELD™ BRSV

Pfizer Animal Health

Bovine Respiratory Syncytial Virus Vaccine, Modified Live Virus

U.S. Vet. Lic. No.: 169

Description: BOVI-SHIELD™ BRSV is a freeze-dried preparation of an attenuated strain of BRSV propagated on an established bovine cell line, plus a sterile diluent used to rehydrate the freeze-dried vaccine.

Contains gentamicin as preservative.

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1145